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July 5, 2000

Mr. James C. Morrison
CDER Ombudsman (HFD-1)
5600 Fishers Lane
Rockville, MD 20857

Dear Mr. Morrison:

In writing this letter I am not sure if it is properly addressed, but would like a copy of it to Dr. Janet Woodcock, Director of CDER, and any other person(s) involved in the decision making process for OTC drug approvals.

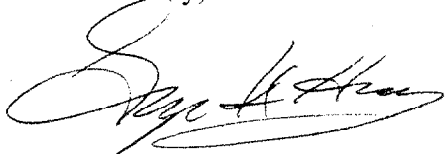
An article was published in the Arkansas Democrat Gazette (July 3, 2000-Pg. 4A) titled "FDA rethinks scope of over-the-counter drugs" which is very disturbing. The idea of allowing such drugs as cholesterol and blood pressure lowering drugs, and even antibiotics to be sold over the counter without a doctor's prescription is WRONG. My doctor has closely monitored my intake of Mevacor and Vasotec, increasing the dosage based on blood test results. My wife has similar doctor's direction for her Cardizem and Vaseretic intake. Our doctors know how to evaluate our conditions and the corresponding side effects. In addition, there are several other drugs we also take which have possible interrelated effects on one another. Placing the drugs OTC will endanger public health of all users.

Another side effect, which may not have been considered, is COST of these drugs with OTC vs. prescription drugs. At a time when our politicians are concerned about the cost of drugs, and trying to make prescription drugs available to everyone, going to OTC will make the drugs ineligible for INSURANCE COVERAGE. Sure the insurance and drug companies would have massive profits by going OTC, but the American citizen (particularly the senior citizens who are by far the largest users of these drugs) would be without a means to pay for them. At age 70, and my wife 65, it will cost us by OTC over \$2,000.00 per year just for these drugs, which are currently under insurance coverage as prescription drugs.

As above, most people will be faced with the same problems, including the younger working people with company sponsored insurance programs. Going OTC will eliminate our insurance coverage for drugs-----create a danger for users---and the FDA should consider these factors. We all know the drug industry has great lobbying power with their money available through the price charged for drugs, however we pray the FDA will see through this for the citizens of this great country.

Sincerely,

00N-1256



CH 206

DA rethinks scope of over-the-counter drugs

BY MARLENE CIMONS
LOS ANGELES TIMES

WASHINGTON — It was regarded as a radical idea nearly 30 years ago when the Food and Drug Administration decided to allow certain prescription drugs to be sold over the counter.

Since 1972, hundreds of medicines — from pain relievers to nasal agents — have moved behind pharmacists' counters and onto store shelves and into consumers' hands with few adverse consequences.

The FDA is considering expanding the scope of over-the-counter medicines to include such products as cholesterol- and blood pressure-lowering drugs, birth control pills, even antibiotics. The suggestion is provoking as much debate as it did then.

Opponents argue that, given the agency's current obsession with further empowering Americans, it is making their own decisions about what medicines to take is

There is a higher level of consumer awareness, with people more interested in self-care," Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research, explaining the agency's decision to begin exploring the issue. "Also, we have safer medicines today."

People who raise the red flag that many of these drugs — usually those used to treat chronic conditions, often with no side effects — cannot be used safely unless a doctor monitors them. In the case of antibiotics, for example, worry that the growing problem of bacterial drug resistance is worsened by more indiscriminate use.

"Already troublesome" number of drug interactions and unexpected toxic side effects — often can be detected only through laboratory tests — could be even more dangerous without a physi-

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— Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research

cian's involvement, warned Dr. Sidney Wolfe, director of Public Citizen's Health Research Group, at a two-day public hearing on the issue last week.

The debate was prompted by two drug manufacturers who are seeking over-the-counter status for their cholesterol-lowering drugs. The agency plans to look specifically at their cases later this month. If FDA officials allow them to make the switch, it could open the door for numerous other prescription-only drugs to become more easily available.

Wolfe, who opposes over-the-counter status for cholesterol-lowering drugs, argued that cholesterol drug treatment requires close physician supervision, including periodic checkups and blood tests. He fears that these safeguards would wane with dangerous consequences if such drugs became available without a doctor's order.

"Medical checkups are needed for determining if the drug is working and for assessing other aspects of disease progression," including the possibility of liver toxicity, he said.

But Dr. Jeffrey Anderson, chief of the division of cardiology at the University of Utah, argued that giving over-the-counter status to Merck's anti-cholesterol drug Mevacor (also known by its chemical name lovastatin) is safer, given the current consumer tendency to use unregulated nutritional supplements for every ailment, including some, such as red yeast rice, touted to lower cholesterol.

If Merck's drug were made avail-

able over the counter, it would ensure "reliable dosing and purity" in a "regulated, educational environment," which is not necessarily the case with diet supplements, Anderson said. Also, having the drug available over the counter could benefit those with mildly high cholesterol who generally are not considered candidates for higher-dose drug therapy.

The FDA will convene a panel of scientific experts this month to consider the requests of Merck & Co. and Bristol-Myers Squibb, who want to market low-dose versions of their cholesterol-lowering drugs. With their patents running out, both companies want to encourage brand loyalty among patients.

The FDA is expected to consider other classes of drugs as well — birth control pills for "morning after" use — likely to incur the wrath of abortion opponents — and antibiotics. Just the thought of putting antibiotics on drugstore shelves makes many infectious disease specialists extremely nervous.

"Some infectious diseases ... are actually worsened by antibiotics," said Dr. Robert T. Schooley, head of infectious diseases at the University of Colorado Health Sciences Center. Often, there are also unexpected and potentially fatal side effects to some antibiotics. And, experts believe, consumers already demand antibiotics too often for the wrong reasons — such as viral infections, which antibiotics do nothing to cure, and which contribute to the serious problem of microbial resistance to drugs.

For its part, the FDA says that it

will not make a sweeping policy change but instead will consider each drug separately.

"We will take the drugs one at a time, and we will be making case-by-case decisions on each drug that comes up," Woodcock said, pointing out that it is up to drug manufacturers to ask the FDA for such a change in status. "They have to apply, and there is an extensive process."

Wary of unsupervised drug use, but eager to empower patients, some health advocates have proposed an alternative to over-the-counter medicine: the creation of an in-between status, unofficially dubbed "under the counter."

It would make drugs available without a prescription, but they would not be on store shelves. Consumers would have to ask for them, ensuring the involvement of a pharmacist.

Pharmacists like the concept — they increasingly view themselves as an information bridge between physicians and consumers, particularly in the managed-care era when doctors have less time to spend with patients.

When over-the-counter status is questionable, "the use of a system of marketing products through pharmacists should be considered," said Rebecca Chater, a North Carolina pharmacist speaking for the American Pharmaceutical Association, the professional society of pharmacists.

This, she said, "would expand access beyond the traditional system, while maintaining health-professional interaction." Also, data gathered from the experience "could be used to support the transition from prescription to full [over-the-counter] availability."

But the pharmaceutical industry is cool to the idea, fearing that it could signal a pullback of some products now enjoying over-the-counter status.